MORRE, ET AL. Appl. No. Unassigned US National Phase of PCT/EP2003/008701 February 2, 2005

REMARKS

The specification has been amended to include a cross-reference to the parent applications and the abstract.

Claims 1-55 have been canceled, without prejudice. Claims 56-110 have been added and are pending. No new matter has been added.

Return of an initialed copy of the attached PTO 1449 Form, pursuant to MPEP § 609, is requested.

The attached paper and computer readable copies of the Sequence Listing are the same. No new matter has been added.

Acceptance of the attached drawings, or specific objection or rejection of the same, is requested.

An early and favorable action on the merits of the claimed invention is requested.

Respectfully submitted,

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PATENT APPLICATION

ABSTRACT

The present invention relates, generally, to the fields of immunology and molecular biology. The invention discloses, more particularly, new and improved interleukin-7 drug substances, corresponding specific immunoreactive antibodies, as well as compositions comprising the same, their preparation and uses. The invention also discloses methods to characterize the impurity profile of a r-hIL-7 drug substance used for therapeutic purpose, as well as optimized nucleotide sequences encoding mammalian IL-7, recombinant expression vectors and methods for preparing and purifying said polypeptides. The present invention stems from the unexpected discovery that the long term activity of recombinant IL-7 is mostly expressed by a specific conformer and that other conformers, potential product-related substances, product-related impurities, and process-related impurities, which would normally be included in the specification of the drug substance and/or drug product, although bioactive, should be strictly minimized because they are able to trigger an immune reaction against the desired IL-7 molecule.